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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Masaaki Yoshikawa

2005-0460 A

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05/28/2009

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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/529,552		YOSHIKAWA ET AL.	
	Examiner		Art Unit	
	ALICIA R. HUGHES		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 9-16 are pending and the subject of this Office Action. Applicants cancelled claims 1-8 in their remarks of 18 February 2009.

Claim Rejection - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 is drawn in pertinent part to a “prostaglandin D₂ related substance.” However, there is not mention of a prostaglandin D₂ related substance in the specification. Furthermore, the current phraseology describes the functionality of the subject matter without a clear structure to define what the subject matter actually is.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that the “applicant must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’

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inquiry, *whatever is now claimed.*” *Id.* at 1117. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Id.* at 1116.

Based on the phraseology prostaglandin D₂ related substance, the skilled artisan cannot envision the detailed chemical structure envisioned by the Applicants. Adequate written description requires more than a mere statement that it is part of the invention. *See Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen, Inc. v. Chugai Pharmaceutical Co., rtd.*, 18 USPQ2d 1016.

Claim Rejections - 35 U.S.C. §112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-16 are rejected under 35 U.S.C. §112, second paragraph for indefiniteness. The phraseology “including human” in claims 9, 10, and 11 (with claims 12-16 depending from claim 11) is relative and therefore, renders the claim indefinite. The phraseology “including human” is exemplary and unclear as to whether it represents a controlling limitation.

Claim 9 is rejected under 35 U.S.C. §112, second paragraph for indefiniteness, also. The phraseology “prostaglandin D₂ related substance” is indefinite in claim 9, because its intended relationship is unclear. For example, the skilled artisan is uncertain as to whether the Applicants intended a functional relationship and/or a chemical relationship, etc.

Claim Rejection – 35 U.S.C. §102(b)

The following is a quotation of 35 U.S.C. §102(b), which forms the basis for all obviousness rejections set forth in this Office Action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. §102(b) as being anticipated by Exton, Michael, et al., “Behaviorally Conditioned Anorexia: Role of Gastric Emptying and Prostaglandins,” *Physiology & Behavior*, Volume 58, Issue 3, Pages 471-476 (September 1995)[hereinafter referred to as “Exton et al”].

Exton et al teaches that conditioned anorexia is the result of conditioned inhibition of gastric emptying, a process mediated by conditioned alterations in prostaglandin levels (Abstract; Page 475, Col. 2, Para. 3). And moreover, the rate of gastric emptying influences food intake (Page 475, Col. 2, Para. 1). Conclusively, “conditioned anorexia is PG dependent” (Page 475, Col. 1, Para. 1) ... and “PGs [prostaglandins] are essential mediators of pyrogen induced gastroparesis” (Page 475, Col. 2, Para. 1).

In short, Exton et al teaches that the conditionability of LPA-induced anorexia is PG dependent, gastric emptying is also conditionable and PG dependent, and conditioned anorexia is due to conditioned retardation of gastric emptying, mediated by prostaglandins at a central site (Page 475, Col. 2, last paragraph).

Applicants’ properly note in their response of 18 February 2009 that the claimed inventions are directed to a method of *stimulating* food intake by the administration of PGD2 or a PGD2 agonist and *inhibiting* food intake by the administration of a PGD2 antagonist. See

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Applicants' arguments of 18 February 2009 at page 6. The effect of this "stimulating" and "inhibiting" is regulation, which brings claim 9 within the purview of Exton et al. Thus, the 102(b) rejection of claim 9 is maintained.

In view of the foregoing, claim 9 is clearly anticipated.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

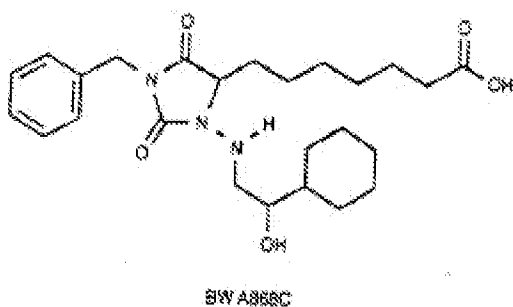
Claims 9-16 are rejected under 35 U.S.C. 103(a) as being obvious over Exton et al in view of Williams, G.W. et al, "Pharmacology and Autoradiography of Human DP Prostanoid Receptors Using [³H]-BWA868C, A DP Receptor-Selective Antagonist Radioligand," *British Journal of Pharmacology*, Vol. 131, Pages 1025-1038 (2000) and in further view of Sharif, Najam, et al, "Affinities, Selectivities, Potencies, and Intrinsic Activities of Natural and Synthetic Prostanoids Using Endogenous Receptors: Focus on DP Class Prostanoids," *The Journal of Pharmacology and Experimental Therapeutics*, Vol. 293, No. 2, Pages 321-328 (2000).

The teachings of Exton et al, *supra* and in this Office's actions made previously of record are incorporated herein by reference in their entirety.

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Applicants argue that the claimed invention is not obvious solely, because Williams et al and Sharif et al fail to remedy the deficiency in Exton et al. This argument is not persuasive because the rejection of Exton et al over claim 9 stands.

Williams et al teach that prostaglandins such as PGD₂, PGE₂, PGF_{2α}, PGI₂ represent the major endogenously generated prostanoids from arachidonic acid which may have many different functions in the mammalian body, and PGD₂ is implicated in the mediations and regulation of, for example, sleep, hormone secretion, and body temperature, amongst other functions (Page 1025, Col. 1). Williams et al also teach that PGD₂ interacts to via coupling to Gs-protein receptors to adenylyl cyclase, and initiates the production of cyclic AMP. The PGD₂-sensitive receptor, known as the DP receptor, is inhibited by BWA868C (Page 1025, Cols. 1-2, first and second paragraphs, respectively), and BWA868C, the structure shown below, is the subject of this invention.



Williams et al also teach that unlabelled BWA868C has a high affinity for [³H]-PGD₂ binding to the DP receptor on human platelet membranes, but a very low affinity for the EP₃, FP, IP and TP receptors (Page 1034, Col. 1, Para. 4). As a result, [³H]-BWA868C is known as a

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stable, high-affinity and selective antagonist radioligand of relatively high specific activity (Page 1036, Col. 1, Para. 1).¹

Sharif et al teach that BWA868C inhibits PGD₂, but while behaving as a bona fide antagonist, it also exhibits potent agonist activity (Page 327, Col. 2, Para. 2).

One of ordinary skill in the art would have been motivated to combined the teachings of Exton et al with the teachings of Williams et al and Sharif et al due to the overlapping scope and analogousness of the subject matter involved, most notably prostaglandins, their types and the scopes of their pharmacological properties and activities.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings Exton et al with the teachings of Williams et al and Sharif et al to make a pharmaceutical composition comprising a prostaglandin D₂ antagonist or agonist for the regulation of food intake.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

¹ U.S. 6,743,793 is noted in PTO Form 892 as a general reference germane to the subject matter of the claimed invention and associated rejections.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614